OroTect

Epigenetic Markers for Diagnostics of Recurrent Head and Neck Tumors

OroTect - Our Vision for Recurrence Diagnostics

At a glance

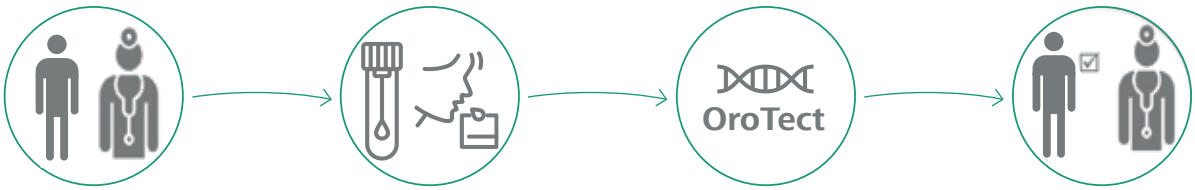
Liquid biopsy in tumor follow-up care

Quick and easy diagnostics for head and neck tumors

Non-invasive specimen sampling

The diagnosis of recurrence patients with head and neck tumors presents a significant challenge in clinical practice. Within the first two years after the surgical removal of the tumor, the risk of tumor recurrence is high, making close monitoring essential. To date, simple diagnostic tools for the early detection of recurring tumors has been lacking.

OroTect is intended as a future in-vitro diagnostic tool for intensive monitoring of tumor patients in follow-up care. **OroTect** examines saliva or oral swab samples for tumor-specific DNA changes (DNA methylation) to detect recurrences before they become visible at a macroscopic level.



Step 1:
Follow-up examination
Visit with the treating specialist or general practitioner

Step 2:
Liquid biopsy collection
Collection of saliva or swab sample and shipment to a laboratory

Step 3:
OroTect Procedure
Analysis of tumor markers (DNA methylation) in human genetic material

Step 4:
Result
Confirmation of recurrence-free status or referral for specialist evaluation

A liquid biopsy can also be regularly performed by general practitioners. Complex imaging procedures can thus be used more selectively, accelerating treatment decisions. **OroTect** will provide a non-invasive method for monitoring patients with head and neck tumors.

OroTect in follow-up care

OncSaliva, a non-interventional, prospective study, is currently testing a set of tumor markers in practical application. Over a period of two years, standard diagnostics and **OroTect** will be used in parallel.

During each follow-up examination, head and neck tumor patients provide a saliva or swab sample at the clinic. Alongside clinical treatment, each sample is examined for the recurrence of **OroTect** tumor markers.

The correlation between the **OroTect** results and the course of therapy will demonstrate that local recurrences, secondary cancers, or tumor residues can be detected and treated earlier using the PCR-based method (**see figure 1**).

☑ **Easy sample material**

☑ **Early recurrence diagnostics**

Patient progression of regular follow-up care and implementation of OroTect in the course of the OncSaliva study

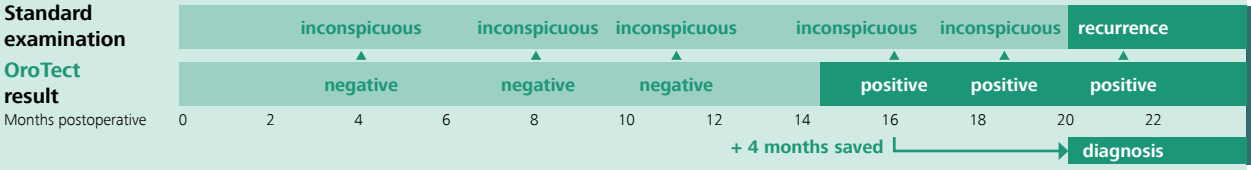


Figure 1 **Example of a patient course with regular follow-up care and OroTect implementation**
The figure shows the amount of time OroTect can save. Compared to standard diagnostics, OroTect was positive four months before the recurrence was found and could therefore have resulted in faster medical action.

Advantage over Standard Diagnostics

This example demonstrates that **OroTect** can detect a local recurrence much earlier compared to standard diagnostics. Interim study results show that diagnostics with OroTect can provide a significant time advantage.

Technical Details

Simple sample collection:
Saliva samples, oral swabs

OroTect result:
Objective assessment using molecular biology detection method

Implementation in the laboratory:
Bisulfite treatment to fix the methylation pattern, followed by methylation-specific qPCR

Analysis:
Assessment of DNA methylation markers, as well as reference markers, and algorithm-based evaluation

OroTect – head and neck tumor diagnostics of the future

- Simple liquid biopsies (saliva and swab) detect tumor cell DNA at an early stage.
- Saves time compared to standard diagnostics. This can be decisive for the success of treatment.
- Saves resources by potentially reducing time-consuming and expensive diagnostics.
- In the future, could also be used to clarify abnormal findings in secondary prevention.

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MOLECULAR CANCER DIAGNOSTICS

OroTect – a non-invasive diagnostic test, based on DNA methylation markers, closes the existing gap in the follow-up care of head and neck tumors.

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